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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/807,603	04/16/2001	Satoru Todo	067242/0148	2083

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FOLEY AND LARDNER  
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3000 K STREET NW  
WASHINGTON, DC 20007

EXAMINER

KWON, BRIAN YONG S

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 06/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/807,603

Applicant(s)

TODO, SATORU

Examiner

Brian S Kwon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 3/28/03.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 48, 101 and 104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 48, 101 and 104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                             | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

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## **DETAILED ACTION**

### ***Status of Application***

1. Acknowledgment is made of applicant's filing of Amendment filed on March 28, 2003 along with Transmittal of Formal Drawings. By the amendment, claims 1-47, 49-100, 102-103 and 105 have been cancelled. Claims 48, 101 and 104 are currently pending for the prosecution on merits.

### ***Drawings***

2. The proposed drawing correction filed on March 28, 2003 are accepted by the Examiner.

### ***Withdrawal of Allowable Subject Matter***

3. The Examiner indicated in Office Action mailed on October 28, 2002 that the claimed method of using sPLA2 inhibitor represented by Formula (I) for the treatment or preventing ischemia reperfusion injury is novel over the prior art of references (page 8, para. 3 thru page 9, para. 3 of the Office Action).

In reconsideration, the Examiner withdraws from the earlier indication of allowable subject matter.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 101 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Khau et al. (US 5986106)

Khau teaches the use of [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid and its sodium salt as sPLA2 inhibitor for treating septic shock (column 1, lines 10-14; column 12, line 52; Example 1).

Although the reference is silent about the use of the claimed sPLA2 for preventing ischemia reperfusion injury, administering of the referenced sPLA2 inhibitor such as [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid to the subject inherently possesses the claimed protective utility of preventing ischemia reperfusion injury. Therefore, the reference clearly anticipates the claimed invention.

### ***Claim Rejections - 35 USC §103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

5. Claims 48, 101 and 104 are rejected under 35 U.S.C. 103(a) as obvious over Sonnino et al. (Digestive Diseases and Sciences, Vol. 42, No.5, May 1997) in view of Khau et al. (US 5986106).

Sonnino discloses PX-13 as a sPLA2 inhibitor, and it further states that PLA2 released during ischemia is a type-II substance, that sPLA2 contributes to ischemic reflow, and that control of sPLA2 activity protects tissue fragments from ischemia and reflow in cold preservation graft study (abstract and page 973, column 1, para. 2). More specifically, Sonnino teaches or suggests the use of sPLA2 inhibitors for ischemic-reperfusion injury (page 980, column 1, lines 1-13).

Khau teaches the use of the claimed compounds represented by the formula (I), namely [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid and its sodium salt, as sPLA2 inhibitor (column 12, line 52; Example 1) .

The teaching of Sonnino differs from the claimed invention in the use of the specific sPLA2 inhibitor represented by the formula (I) for the treatment of ischemia reperfusion injury. To incorporate such teaching into the teaching of the Sonnino, would have been obvious in view of Khau teaches the use of [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid and its sodium salt as sPLA2 inhibitor.

One having ordinary skill in the art would have known that sPLA2 contributes to ischemia-reperfusion injury and inhibition of sPLA2 would be useful in treating ischemia-reperfusion injury. One having ordinary skill in the art would have expected that any compounds that inhibit the secretion of sPLA2 would have similar therapeutic utility in the treatment of

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ischemia-reperfusion injury. Furthermore, one having ordinary skill in the art would have been motivated to administer well known sPLA2 (as taught by Khau), with the reasonable expectation of success, to treat ischemia-reperfusion injury. One having ordinary skill in the art would have motivated to make such modification to extend the usage of the claimed sPLA2 inhibitor, namely [[3-(2-amino-1,2-dioxoethyl)-2-ethyl-1-(phenylmethyl)-1H-indole-4-yl]oxy]acetic acid, in the treatment of ischemia-reperfusion injury.

Applicant has presented no evidence to establish the unexpected or unobvious nature of the claimed invention, and as such, claims 48, 101 and 104 are properly rejected under 35 U.S.C. 103.

### Conclusion

6. No Claim is allowed.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (703) 308-5377. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax number for this Group is (703) 308-4556.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

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Brian Kwon

**ZOHREH FAY**  
**PRIMARY EXAMINER**

GROUP 1600

A handwritten signature in black ink, appearing to read "Zohreh Fay", written in a cursive style.